DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR DISEASE CONTROL AND PREVENTION
National Center for HIV, STD and TB Prevention
Division of Tuberculosis Elimination

Advisory Council for the Elimination of Tuberculosis
July 26-27, 2006
Atlanta, Georgia

Record of the Proceedings

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ACET Members

Dr. Masae Kawamura, Chair
Dr. William Burman
Dr. Michael Fleenor
Dr. Jennifer Flood
Dr. Richard Fluck
Dr. David Gonzales
Ms. Harriett Gray
Mr. Shannon Jones III
Ms. Sara Loaiza
Dr. Barbara Seaworth

***Ex-Officio* and Liaison Members**

Dr. William Baine (AHRQ)
Dr. John Bernardo (NTCA)
Dr. James Cheek (IHS)
Dr. Richard Ehrenberg (NIOSH)
Dr. Sheldon Morris (FDA)
Dr. Edward Nardell (IUATLD)
Dr. Gary Roselle (VA)
Dr. Diana Schneider (DIHS)
Ms. Rachel Stricof (APIC)
Dr. Theresa Watkins-Bryant (HRSA)
Dr. Mamodikoe Makhene (NIH)

Designated Federal Official

Dr. Ronald Valdiserri,
Executive Secretary

CDC Representatives

Dr. Kevin Fenton, NCHSTP Director
Dr. Kenneth Castro, DTBE Director
Dr. Gregory Armstrong
Ms. Sandy Athomsons
Dr. Martin Cetron
Dr. Hazel Dean
Dr. Nickolas DeLuca
Dr. Heather Duncan
Ms. Mollie Ergle (Contractor)
Ms. Paulette Ford-Knights
Ms. Judy Gibson
Dr. Theresa Harrington
Dr. Kashef Ijaz
Dr. John Jereb
Ms. Loretta Johnson
Dr. Dolly Katz
Ms. Ann Lanner
Dr. Anthony Martin
Ms. Pamela McSpadden
Dr. Mary Naughton
Dr. Thomas Navin
Dr. Janet Nicholson
Dr. Luis Ortega
Dr. Drew Posey
Dr. Daniel Reidford
Ms. Margie Scott-Cseh
Dr. Salaam Semaan
Dr. Phillip Talboy
Mr. Victor Tomlinson, Jr.
Ms. Cheryl Tryon
Dr. Andrew Vernon
Dr. Wanda Walton
Dr. Cornelia White
Ms. Kai Young

Guest Presenters and Members of the Public

Mr. Peter Mamacos (Office of the Global AIDS Coordinator)
Ms. Carol Pozsik (National Tuberculosis Controllers Association)
Dr. Rachel Royce (Research Triangle Institute International)
Mr. John Seggerson (National Coalition for the Elimination of Tuberculosis)

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ADVISORY COUNCIL FOR THE ELIMINATION OF TUBERCULOSIS
July 26-27, 2006
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Draft Minutes of the Meeting

The Department of Health and Human Services (HHS) and the Centers for Disease Control and Prevention (CDC) convened a meeting of the Advisory Council for the Elimination of Tuberculosis (ACET). The proceedings were held on July 26-27, 2006 at CDC's Corporate Square Facility, Building 8, in Atlanta, Georgia.

Opening Session

Dr. Masae Kawamura, the ACET Chair, called the meeting to order at 8:35 a.m. on July 26, 2006. She welcomed the attendees to the proceedings and opened the floor for introductions. The list of participants is appended to the minutes as Attachment 1.

Dr. Ronald Valdiserri, the ACET Executive Secretary, announced that ACET meetings are open to the public and all comments made during the proceedings are a matter of public record. Members should be mindful of potential conflicts of interest identified by the CDC Committee Management Office and recuse themselves from voting or participating in these discussions.

Dr. Valdiserri noted that the terms of the ACET Chair and three members expired in June 2006: Dr. Kawamura, Dr. David Gonzales, Ms. Harriett Gray and Ms. Sara Loaiza. The participants applauded the outstanding contributions the outgoing members made to ACET, CDC and HHS during their service. Dr. Michael Fleenor will begin serving as the new ACET Chair during the next meeting. Dr. Valdiserri informed ACET that biographical sketches were distributed for the four new members: Dr. Ana Lopez de Fede, Mr. Joseph Kinney, Dr. Mashario Narita and Ms. Sirlura Taylor.

In addition to the four outgoing ACET members, Dr. Kawamura announced that Dr. Valdiserri accepted a new position with another agency. She presented Dr. Valdiserri with a plaque to formally acknowledge his distinguished service as the ACET Executive Secretary. She pointed out that Dr. Valdiserri's tremendous leadership was the cornerstone of ACET

providing solid guidance to CDC and HHS. The participants applauded Dr. Valdiserri's excellent contributions to ACET and wished him well in his new position.

Dr. Diana Schneider, the *ex-officio* representative for the Division of Immigration Health Services (DIHS), presented Dr. Valdiserri with a token of appreciation for his support of DIHS. She noted that Dr. Valdiserri was directly responsible for expanding ACET's membership several years ago to include a DIHS representative. The participants applauded Dr. Valdiserri's valuable efforts in spearheading the partnership between ACET and DIHS.

Update by the Director of the National Center for HIV, STD and TB Prevention (NCHSTP)

Dr. Kevin Fenton covered the following areas in his report. CDC's 21 health protection goals to harmonize activities throughout the agency and maximize health protection represent a new and exciting development. The goals were designed to achieve four objectives. First, CDC's coordinating centers, divisions, subject matter experts, and centers, institutes and offices (CIOs) will be engaged in assessing, planning and establishing priorities for activities.

Second, key activities and performance indicators will be identified and aligned throughout CDC to increase efficiency, effectiveness and health impact. Third, collaboration will be enhanced across CDC and with partners. Fourth, activities, products, tools and reports to support the priorities will be highlighted.

CDC grouped the 21 health protection goals into four categories. The "people" goals will focus on ensuring that all persons achieve their optimal life span with the best possible quality of life in every stage of life. The "preparedness" goals will focus on ensuring that persons in all communities are protected from infectious, environmental, occupational and terrorist threats. The remaining two categories are "places" and "global" goals.

CDC is now accepting nominations for staff to join goal teams to conduct the following activities. Data and opportunities that are relevant to goals will be analyzed. Input from CDC staff, partners and the public will be integrated to identify objectives, strategies, actions and measures to accelerate progress toward achieving goals. Oversight will be provided to CDC's organizational components to implement strategies, actions and measures to achieve goals. Progress toward achieving goals will be monitored by reviewing and analyzing data on intervention and research implementation. NCHSTP will extensively engage ACET in the health protection goals process to ensure that TB is included in this effort.

CDC released its 2006-2010 Strategic Diversity Plan (SDP) on June 1, 2006 to develop a more diverse workforce at all levels within the agency. The SDP defines "diversity" as a

resource that is fundamental to organizational excellence. Affirmative action, the value of diversity and management of diversity are highlighted as three SDP approaches that may be used at different times or simultaneously by various CDC organizational components. CDC will take the following actions to manage diversity: (1) improve the full use of all human resources within the organization; (2) make an organizational commitment to provide quality service and achieve increased productivity; and (3) focus on creating a diversity-friendly management system.

CDC formed a Public Health Practice Council (PHPC) to explore public health practice issues; promote the translation of science into effective public health action; and shape and guide the implementation of strategies to improve public health practice nationwide. Each CDC coordinating center and CIO will serve as a standing PHPC member and participate in monthly meetings sponsored by the Office of the Chief of Public Health Practice.

PHPC will also focus on the accreditation of public health agencies. This activity will be conducted by state and local health departments outside of CDC, but with CDC's full support. The voluntary process will be designed to improve the quality of public health practice and provide a forum for public health advocacy within the United States. The public health agency accreditation process is now in the early stages of development. Potential partners are being identified to engage in initial discussions of the advantages and disadvantages of accrediting public health agencies and implementation of this process.

NCHSTP is now functioning as four national centers with the addition of the Division of Viral Hepatitis (DVH). Diligent efforts have been made over the past six months to ensure the full integration of DVH into NCHSTP. The Coordinating Center for Infectious Diseases (CCID) expects to stand up its Strategic Business Unit on August 29, 2006, Strategic Science and Program Unit on September 18, 2006, and Communications Office on October 1, 2006. A workgroup was formed to specifically focus on informatics and enterprise. CCID is involved in ongoing planning activities for pandemic influenza preparedness. Dr. Kenneth Castro, the Division of Tuberculosis Elimination (DTBE) Director, is representing NCHSTP in this effort.

NCHSTP conducted or participated in several events following the February 2006 ACET meeting. World TB Day was held on March 24, 2006. The "Stop Tuberculosis in the African American Community Summit for Success" was convened on May 16-17, 2006 to focus on TB racial/ethic disparities in the United States. During the summit, successful models in mobilizing communities in the fight against TB were reviewed and novel strategies were identified to address the issue of TB in the African American (AA) community. Dr. Fenton made site visits to TB programs in Botswana, California, Chicago and New York in January-July 2006. Leadership priorities for FY'07 are currently being developed.

The HHS Secretary exercised a 1% transfer authority in the FY'06 TB budget that resulted in $94,401 being transferred from DTBE to support HHS-wide activities. The House and Senate budgets proposed level funding of $137.4 million for the FY'07 TB budget.

Two significant changes occurred in NCHSTP's personnel following the February 2006 ACET meeting. Dr. Valdiserri spent most of his 18 years at CDC as the NCHSTP Deputy Director, but he will no longer serve in this role as of September 3, 2006. Dr. Valdiserri has accepted a new position as the Chief Consultant for the Public Health Strategic Health Care Group at the Veterans Health Administration in Washington, DC.

Dr. Ida Onorato, the NCHSTP Deputy Associate Director, lost her battle with cancer on May 31, 2006. A memorial service will be held for Dr. Onorato on July 31, 2006 at the Emory University Cannon Chapel. The participants acknowledged Dr. Onorato's tremendous contributions to infectious disease prevention and control at both domestic and international levels.

Other key personnel changes include the retirement of the NCHSTP Associate Director for Science in May 2006 and the temporary assignment of the NCHSTP Associate Director for Communications to the CDC Office of the Director. NCHSTP has designated staff to act in these two positions during the search for permanent replacements. Dr. Fenton has prioritized NCHSTP's acting positions and hopes to announce permanent appointments by the end of the 2006 calendar year.

Dr. Fenton concluded his presentation by responding to concerns ACET raised at previous meetings. First, NCHSTP will ensure that TB is included in its 2006 strategic priorities for infectious disease health disparities. Second, NCHSTP will continue to implement its traditional approaches to translate science into public health practice, such as developing and disseminating guidance documents, publishing articles in the *Morbidity and Mortality Weekly Report* (*MMWR*), collaborating with partners, and using field staff to apply science in the field. Over the next three months, however, NCHSTP will develop new mechanisms to improve the application of science to public health practice.

Several ACET members emphasized the critical need for NCHSTP to provide regular updates to and obtain input from ACET on the new public health agency accreditation process. This initiative will have significant implications for state and local public health agencies to obtain Institutional Review Board approval to conduct activities. The accreditation process would also result in changes to the current public health definitions of "evaluation" and "surveillance."

CDC pointed out that actions would most likely be taken on the public health agency accreditation process before the next ACET meeting. ACET was advised to identify members to facilitate communications with NCHSTP on this issue prior to the next meeting.

DTBE Director's Report

Dr. Castro covered the following areas in his report. CDC's recommendations on TB prevention and control in correctional and detention facilities were published in the July 7, 2006 edition of the *MMWR*. ACET and two other groups were officially recognized as endorsers of this guidance. The TB Education and Training Network Conference will be convened in August 2006 with a special session for TB program focus points for training. The annual TB Program Manager's Course will be held in October 2006.

A data safety monitoring board review was held in May 2006 on Study 26 for the treatment of latent TB infection (LTBI) with once-weekly isoniazid and rifapentine against daily isoniazid. The review did not demonstrate adverse events or differences requiring termination of the study. To date, >5,000 of the total target population of 8,000 persons have been recruited for Study 26. The Sanofi Aventis rifapentine study in children is underway in the Republic of South Africa. In May 2006, Bristol Myers Squibb announced its intention to cease production of Gatifloxacin due to adverse effects related to hyper- and hypoglycemia. Ongoing trials in many parts of the world will be adversely impacted by the termination in producing this drug.

The TB Trials Consortium (TBTC) will report on new TB drug candidates during its next meeting, including TMC-207 and SQ-109. DTBE will provide an update on these drugs to ACET during a future meeting. The DTBE Clinical and Health Systems Branch was recently restructured. Budget cuts required a stronger focus on data management capacity and less emphasis on the health systems research component. Collaborative efforts are ongoing with the U.S. Air Force to evaluate the QuantiFERON®-TB test (QFT) gamma in tube assay.

Progress is being made on TBTC's Phase II Study 28 to replace moxifloxacin with isoniazid in the initial phase of treatment and analyze culture conversions at two months. Of the total study population of 410 persons, 159 have been enrolled from the United States and overseas with the Uganda site recruiting 60% of the cohort. Enrollment is expected to be completed by April 2007 based on the current rate of enrollment of 30 persons per month. The treatment regimen has shown efficacy. Findings related to pharmacokinetics and responses to therapy in the study population are able to be extrapolated.

At this time, ~33% of TB cooperative agreements were mailed to or received by Western Island, Pacific Island, Central and Eastern project areas. However, grantees have expressed concerns to CDC about delays in receiving awards. Applications for the FY'07 TB cooperative agreements are due to CDC on August 1, 2006. CDC will update the original evaluation plans. Regional Training Medical Consultation Centers (RTMCCs) will be expected to respond to new guidance.

DTBE will collaborate with the CDC Office of Workforce and Career Development to create and launch a TB "wet" laboratory course in June 2007. A training needs survey for the

course was administered to state TB laboratories. The survey results will be used to guide the development of the scope and content of the laboratory course. As of June 30, 2006, 18,386 *Mycobacterium tuberculosis* (*M.tb*) isolates were submitted to DTBE for genotyping. DTBE's goal is to provide universal genotyping for all culture-positive cases.

The TB Epidemiologic Studies Consortium (TBESC) held its semiannual meeting in July 2006 and focused on developing an advisory review process for research concepts, prioritization and recommendations. TBESC is proposing to engage ACET, the National Tuberculosis Controllers Association (NTCA), the TBESC Research Committee and DTBE branch chiefs in this process to provide both internal CDC staff and external practitioners in the field with an opportunity to inform the mission statement of conducting programmatically relevant research.

TBESC's next steps in the advisory review process are as follows: (1) issue a call for research concepts; (2) engage ACET and other partners in developing criteria to prioritize research; (3) ensure data are available to support the priority studies; and (4) make recommendations to Dr. Castro on research agendas DTBE should sponsor. DTBE expects to provide ACET with initial drafts of TBESC's research concepts in the near future.

The Stop TB Now Act of 2006 was introduced in the House and Senate on March 28, 2006. The legislation proposed more direct involvement by CDC and the U.S. Agency for International Development (USAID) in global TB control efforts and the 2006-2015 Global Plan to Stop TB by providing additional resources to these agencies. The Comprehensive TB Elimination Act of 2006 was introduced in the House on July 19, 2006. The legislation recognized DTBE as the "National TB Elimination Program" and requested the allocation of $528 million each year to eliminate TB in a manner consistent with the National Coalition for the Elimination of Tuberculosis funding gap analysis.

The departure of three senior staff members has left a void and required DTBE to initiate recruitment efforts for permanent replacements. Two new Epidemiologic Investigation Service officers have reported to duty in DTBE and are completing the EIS course. DTBE partnered with NTCA and the Georgia Chapter of the American Lung Association to launch the "TB Awareness Walk" on March 24, 2007. DTBE will provide ACET with regular updates as new developments occur in this activity.

Dr. Valdiserri was pleased to announce that Dr. Stephanie Bailey, a former ACET member, recently accepted a position at CDC as the Deputy Director for Public Health Practice.

Update on the Board of Scientific Counselors (BSC)

Dr. Michael Fleenor represented ACET during the May 2006 BSC meeting as one of CCID's six advisory committees. He reported that discussions are being held on restructuring the advisory process. The new role of CCID advisory committees would be to provide guidance

directly to the CCID Director on strategies and priorities to leverage resources and balance research and science. No decisions were made during the May 2006 BSC meeting, but CCID proposed the following process at that time.

The BSC of the National Center for Preparedness, Detection and Control of Infectious Diseases (NCPDCID) (formerly the National Center for Infectious Diseases) would serve as the nucleus of CCID's new advisory structure. The BSC is currently represented by 17 voting members and nine non-voting liaison and *ex-officio* members. The BSC would be expanded to include representatives from ACET and other CCID advisory committees as liaison members. Subcommittees would be formed to provide advice on CCID's research agenda, make recommendations on CCID's scientific direction, and participate in intramural peer reviews and secondary reviews of grants and cooperative agreements.

The rationale for the restructured advisory process is for CCID to improve its cost-effectiveness and efficiency, but Dr. Fleenor has identified potential advantages and disadvantages related to ACET. On the one hand, ACET's representation on the BSC could highlight the importance of TB elimination beyond NCHSTP. On the other hand, the proposed model is not compelling. Some members would be required to attend additional meetings to represent ACET on the BSC and new subcommittees. ACET's input to CCID as a non-voting liaison member on the BSC might be diluted by voting members. Overall, Dr. Fleenor's position was that the success or failure of the proposed advisory structure would depend on implementation of the process and ACET's ability to maintain its autonomous voice for TB elimination.

Dr. Valdiserri reported on events that occurred after the May 2006 BSC meeting. A definite decision was made to transform the NCPDCID BSC into a CCID-wide advisory committee. BSC subcommittees will be formed for NCHSTP and the three other CCID national centers. Dr. Fleenor, as the new ACET Chair, and chairs of other CCID advisory committees will be asked to serve as official liaison members on the new CCID BSC. However, Dr. Valdiserri has recommended that CCID provide advisory committees with flexibility in selecting liaison representatives. This approach will decrease the burden on Dr. Fleenor and other advisory committee chairs in attending multiple meetings for various groups. Dr. Valdiserri emphasized that no decisions have been made on the total number of CCID advisory committees, but the possibility of disbanding ACET or other CCID advisory committees is not being considered.

Dr. Janet Nicholson, the BSC Executive Secretary, provided additional details on the restructured advisory process. Discussions are still underway on whether the number of BSC members, liaisons and *ex-officio* representatives should be increased. ACET's two opportunities to provide input to CCID include serving as a liaison representative on the BSC and a member of the new NCHSTP subcommittee. However, CCID's proposal to form subcommittees for its four national centers has not been approved at the CDC level. Dr. Julie Gerberding, the CDC Director, has expressed a strong interest in establishing BSCs rather than subcommittees. Dr. Gerberding is currently drafting a memorandum to HHS to describe CDC's new approach to obtain external input from federal advisory committees.

Dr. Nicholson announced that a meeting would be held later in the summer of 2006 with the directors of the CCID national centers to discuss voting privileges and other issues related to the restructured advisory process. A decision has already been made to hold meetings for the CCID BSC and national center subcommittees at the same time to reduce the burden on members. However, this format could not be applied if CDC makes a final decision to establish BSCs rather than subcommittees for the national centers.

Dr. Kawamura reminded CDC that ACET is on record with concerns about the potential dilution of its TB elimination voice. ACET is chartered to advise the CDC Director and HHS Secretary. ACET's proposed role as a non-voting liaison representative on the CCID BSC and a member of a new NCHSTP subcommittee would result in more layers and limitations on ACET's ability to provide advice and guidance directly to the CDC Director. Dr. Kawamura also pointed out the additional burden that would be placed on Dr. Fleenor by chairing ACET meetings three times a year and representing ACET on the CCID BSC and NCHSTP subcommittee. Other ACET members expressed uncertainty about the role of new BSCs or subcommittees in improving CCID's cost-effectiveness and efficiency.

Report on the Leaders to Leaders Conference

Ms. Carol Pozsik, the NTCA Executive Director, reported on the "Leaders to Leaders Conference: Engaging the Power of Partnerships" that was held in March 2006. The purpose of the conference was to strengthen CDC's partnerships to continue to make a significant impact on the health and safety of all Americans. Workshops were convened during the conference for 300 diverse partners and CDC leaders throughout the agency to focus on various characteristics of partnerships.

CDC and its partners discussed strategies that could be applied to strengthen collaborations, promote CDC's new health protection goals, and support the goal action planning process for the healthy people, healthy places, preparedness and global goals. A panel of partners discussed their experiences in participating in CDC's Healthy Homes Goal Workshop in February 2006. The panel of partners also described situations in which CDC applied recommendations from the workshop.

The conference served as a forum for CDC to obtain input from partners, provide information about the new health protection goals, and engage in a dialogue with partners to jointly achieve success. The partners and CDC leaders participated in breakout groups to explore approaches for CDC to develop new partnerships, continue to support existing collaborations, and improve communications with partners.

The conference also reinforced the tremendous benefits of partners. Partners bring enormous value to the goal planning process and each other. Partners support the concept of goals and are interested in participating early in the action planning stages. Partners

expect and deserve a return on their investments and are interested in obtaining regular updates toward achieving goals. Partners highly value and support CDC.

The conference resulted in the partners providing CDC with concrete strategies to successfully support and sustain partnerships. A single point of contact should be identified and communicated to partners. Barriers to locating CDC staff should be reduced. More channels of communication should be used. The communications process should be earlier and allow more time for partners to provide input and CDC to respond.

A single consistent message should be delivered. Science should be maintained as the foundation of CDC's activities. CDC should continue efforts to advance the partnership agenda. Opportunities should be created to convene additional partner consultations and conferences. CDC informed the participants that www.cdc.gov/partners had been developed as the new web portal for partners.

Several ACET members were pleased that CDC convened the leadership conference and developed a web site for partners to regularly provide input. However, some members noted that these efforts do not address the disappointing status of ACET's partnership with CDC, such as a decrease in the TB budget, an increase in the bureaucracy with the proposed advisory process, and the potential for ACET's TB elimination voice to be diluted.

Some members also expressed concern that CDC's renewed efforts to obtain input from partners might increase staff time spent in consultations and meetings and reduce staff time in actually conducting activities. The outcomes of these events could potentially be based on politics rather than science. ACET advised CDC to use the new public health agency accreditation process to strengthen communications with and accountability to public health partners at federal, state and local levels.

Update on the Federal TB Task Force (FTBTF)

Dr. Castro explained that FTBTF was established in 1991 in response to the unprecedented resurgence of TB and multi-drug-resistant TB (MDR-TB) in the United States. FTBTF's initial efforts included providing a forum for seven federal agencies and NTCA to communicate and coordinate TB activities and developing a national action plan to combat MDR-TB. However, FTBTF's role is limited to communicating and coordinating activities due to the diverse missions and mandates of the seven federal agencies. Dr. Castro's summary of updates provided by the federal agencies during the May 2006 FTBTF meeting is outlined below.

CDC reported on the domestic and global TB programs and new research and development tools. The CDC National Institute for Occupational Safety and Health reported on the release of its request for applications to study airborne TB. Funds were recently awarded to conduct this study in the Republic of South Africa. The Food and Drug Administration

reported on five new TB vaccines in Phase I and II trials in the United States, Europe, the United Kingdom, Gambia and Tanzania. FTBTF acknowledged the critical need for stronger regulatory capacity and resources to support the TB vaccine trials.

DIHS reported on the increase in TB among persons detained by the Bureau of Immigration and Customs Enforcement (ICE) and the Department of Homeland Security (DHS). In 2001, 41 detainees had TB compared to 142 in 2005. The TB rate of 139 cases per 100,000 detainees was based on both culture-negative and -positive persons. This rate would decrease to 63 cases per 100,000 detainees based on culture-positive persons only.

DIHS emphasized the need for the United States to enhance coordination of TB care with Mexico when detainees are deported due to the increase in TB cases from Honduras, Guatemala and Mexico. Of ICE detainees, 14 medical stays of removal were granted for those diagnosed with TB. DIHS is continuing to address ongoing challenges related to limited funding, continued coordination with countries, restrictions on custody duration, legal barriers, drug resistance and reporting of TB cases.

Several institutes of the National Institutes of Health (NIH) reported on recent TB investments and activities. NIH's agency-wide allocation of $160 million in 2005 to TB research was driven by research grant applications and quality. NIH focused on translational research and TB activities funded by the Gates Foundation to make advances on products.

An NIH institute is focusing on several important issues related to TB vaccines, including (1) the availability of basic research opportunities for Category C agents; (2) the increased cost of TB research due to state-of-the-art technologies; (3) the re-competition of the TB Research Unit contract; and (4) the transformation of AIDS clinical trials into cooperative agreements to provide researchers with more flexibility in conducting TB studies.

An NIH institute allocated $4 million to TB activities in 2005, but did not release any new program announcements. New research is being conducted in India, Thailand and China on drug interactions among HIV, TB and hepatitis C. An NIH institute allocated $17 million to support research on the pathogenesis of TB with genetics and animal, math and human models. Research on tumor necrosis factor-alpha funded by an NIH institute was found to be relevant to TB studies. An NIH center allocated $4 million to build TB scientific research capacity in developing countries.

USAID reported on its allocation of $93 million to TB. However, 5% of these funds will be used to support the Global Drug Facility, the Millennium Development Goal, the 2006-2015 Global Plan to stop TB, and the Stop TB Partnership. The Indian Health Service reported on its ongoing barriers to provide TB to Native Americans/Alaska Natives. At this time, only 40% of the census population is being served.

The Department of Veterans Affairs (VA) reported on a significant decrease in TB cases since the resurgence of TB. VA hospitals reported 982 TB cases in 1992 compared to 64

cases in 2005. The VA developed and implemented a newer system to record and report TB cases and also formed a workgroup to incorporate QFT into TB laboratories. However, the VA has achieved limited uptake on this effort.

Dr. Castro informed ACET that FTBTF formally communicates through annual face-to-face meetings. He welcomed the opportunity to convey ACET's recommendations to FTBTF on topics to address in the future, the potential need to meet more frequently by conference call or other issues.

Dr. Kawamura announced that the HHS Secretary responded to ACET's previous letter. The HHS Secretary noted that FTBTF was recently charged with addressing new TB drugs, but he did not respond to ACET's request for a meeting to discuss TB issues. Dr. Kawamura pointed out that ACET's last meeting with the HHS Secretary was in 2004.

Several members made suggestions to advance ACET's communications on TB issues. CDC could host the next FTBTF meeting the day before the next ACET meeting in Atlanta. The FTBTF members could be invited to attend and provide updates on federal TB issues for their respective agencies. Alternatively, ACET could make a new request to meet with the Assistant HHS Secretary. Overall, ACET emphasized the need for FTBTF to increase its focus and efforts in TB elimination.

Update on the Designation of Civil Surgeons (CSs)

Dr. Mary Naughton, of the CDC Division of Global Migration and Quarantine (DGMQ), covered the following areas in her report. The Immigration and Nationality Act covers the medical examination of aliens, health-related grounds of inadmissibility, and the Refugee Act of 1980. Immigration regulations were also established and the Public Health Service (PHS) enacted legislation in the following areas: (1) waivers for inadmissible conditions; (2) designation and examination requirements for CSs in accordance with PHS regulations; (3) the scope of medical examination of aliens; and (4) medical examinations in accordance with technical instructions (TIs) provided by the DGMQ Director.

Federal funds to comply with these regulations are allocated to the U.S. Citizenship and Immigration Services (USCIS) (formerly the Immigration and Naturalization Service). Local USCIS offices maintain lists of designated CSs. CDC periodically requests these lists to distribute updated TIs to ~3,000 CSs in the United States, but does not receive funding for the designation of CSs.

CSs are charged with examining changes in the status of applications and administering vaccinations to refugees and certain non-immigrants, such as K- and V-visa holders. USCIS sent a letter to the HHS Secretary on May 12, 2006 to propose the following actions. The CS designation should be expanded to essentially all licensed physicians in the United States who have practiced for at least four years and were primary care physicians.

Automatic designation should be instituted without a vetting process. The traditional practice of listing the names of CSs should be discontinued.

Dr. Gerberding's response to the USCIS letter emphasized CDC's position on the proposal. CDC opposed all of the actions proposed by USCIS. CDC provided options and solutions to improve the process of designating CSs. CDC made a commitment to continue to provide technical support and expert advice to USCIS. DGMQ and DTBE met to discuss Dr. Gerberding's letter and notified ACET about these communications.

CDC legal counsel, DGMQ staff, and the USCIS Deputy Director and staff held a conference call in June 2006 and agreed on the following issues. The names of CSs would continue to be listed. CDC was determined to be the best qualified agency to vet CS applications, but no funds are allocated to CDC to conduct this activity. USCIS would collect CS application fees and transfer these monies to CDC for vetting. CDC and USCIS legal counsel would jointly determine the formal transfer process. USCIS would revise the CS rule and incorporate DGMQ's recommendations to strengthen criteria for designating physicians as CSs. The revised CS application would contain questions about the physician's disciplinary actions, malpractice claims, Internet access, license renewals, criminal convictions, formal revocation procedures, continuing medical education, and substance abuse history.

DGMQ would edit the revised CS rule and USCIS would continue to determine actual designation costs. Both agencies would intensify efforts to incorporate specific language into legislative proposals for CDC to formally receive a Congressional appropriation to take total responsibility for the CS program. USCIS would develop a web-based system for CSs to use CDC's electronic disease notification (EDN) system to electronically input I-693 data.

Dr. Naughton described developments that occurred after the June 2006 conference call. USCIS counsel determined that the transfer of CS application fees from USCIS to CDC for proper vetting is possible. CDC and USCIS will convene another conference call the week of July 31, 2006 to discuss the transfer process in more detail. However, Dr. Gerberding's most recent letter to USCIS stated that DGMQ would be unable to take additional responsibility for the CS program for ~18 months due to CDC's priorities related to pandemic influenza preparedness. Dr. Naughton thanked ACET for providing solid input to CDC on the original USCIS letter.

Several ACET members made suggestions for CDC to consider in its ongoing efforts with USCIS to strengthen the process of designating physicians as CSs.

- A web-based educational campaign for TIs should be developed and widely launched to ensure that CSs have a basic understanding and knowledge of TB.
- Collaborative efforts should be undertaken with the Department of State (DOS) to obtain basic profiles of the 3,000 CSs in the United States.

- Profiles of the 3,000 CSs in the United States should be compared to existing lists of providers maintained by states to ensure information from these two sources is consistent. For example, New York State maintains informative, extensive, comprehensive and publicly available profiles on all physicians practicing in the state. The New York State database includes information on the physician's disciplinary actions, malpractice claims, medical school and training history, and all other aspects of the physician's career.
- A portion of the new resources from USCIS should be used to collect data on the performance, outcomes and quality assurance of CSs. Information gathered from this effort should be used to link CSs to RTMCCs. This approach would ensure that CSs are provided with updated information and opportunities to participate in exercises and other training activities related to TB.

Update on the Revised Guidelines to Control TB in Foreign-Born Persons (FBPs)

Dr. Dolly Katz, of DTBE, covered the following areas in her report. The number of TB cases in U.S.-born persons has steadily decreased since 1992, but the incidence of TB in FBPs in the United States has remained fairly stable over time. The current guidelines to control TB in FBPs were published in 1998, are outdated, and do not represent key changes that have occurred over the past ten years. Policies related to immigration screening, HIV exemptions and oversight of CSs have changed. New diagnostic tools have been developed, such as three generations of the QFT TB test and the T-spot test. Immigration patterns and the TB epidemiology in the United States have changed with FBPs now representing the majority of U.S. cases.

TBESC will produce new data based on enhanced surveillance to identify missed opportunities for the prevention of TB in FBPs. Of 1,500 interviews planned with FBPs newly diagnosed with TB, 1,419 have been completed. Information collected from the interviews will be combined with clinical data from CDC's TB Information Management System and DGMQ's data on B conditions. Data from the TBESC project will be provided to the workgroup that will revise the FBP guidelines.

ACET's Foreign-Born Workgroup emphasized the need for a new focus and identified several priority topics that should be strengthened in the revised FBP guidelines: (1) pre- and post-entry diagnosis, screening and treatment; (2) funding for TB programs; (3) care issues, including access, cost and cultural differences; (4) community collaboration; (5) pediatric issues; (6) cross-border CI; (7) use of BCG; and (8) refinement of targeted testing.

CDC has taken several actions to revise the FBP guidelines. A workgroup was formed based on nominations from CDC, ACET and other partners with representation by federal agencies, state and local TB control agencies, clinicians, immigration officials, non-governmental organizations (NGOs), minority health organizations and patient advocacy

groups. The workgroup was charged with determining the focus and purpose of the revised FBP guidelines; reaching consensus on evidence-based guidance; and updating the guidelines with practical and useful information.

CDC and ACET members held informal meetings, but the entire workgroup will attend a face-to-face meeting in Atlanta on November 16-17, 2006 to approve the outline of the FBP guidelines, form small subgroups and prepare a timeline. The subgroups will maintain contact through conference calls. A small writing group will be formed to finalize the guidelines as a joint ACET/CDC document. CDC expects to initiate the clearance process by December 2007.

ACET was extremely pleased about CDC's progress in revising the FBP guidelines. Several members advised CDC to obtain independent feedback from an external peer review panel or focus groups before initiating the clearance process.

Report on the "Stop TB in the African American Community Summit for Success"

CDC Perspective. Dr. Nickolas DeLuca, of DTBE, described CDC's perspective of the summit that was held on May 16-17, 2006. The summit represented a collaborative effort between CDC and Research Triangle Institute (RTI) International with funding and support provided by the NCHSTP Office of Health Disparities, RTI International and Cellestis. The rationale for the summit was due to the continued burden of TB in racial/ethnic minority groups despite the decline in overall TB rates in the United States. Based on 2004 data, 82% of all reported TB cases occurred in racial/ethnic minority groups and 45% of TB cases reported in U.S.-born (USB) persons were among AAs. The TB case rate of 9.2/100,000 in USB AAs is >8 times higher than the case rate of 1.1/100,000 in whites.

Of 2,675 TB cases reported in AAs in 2004, 70% were among males with a median age of 46 years. Data from 2000-2004 showed a high concentration of TB cases among USB AAs in the Southeast and Northeast. CDC recently reviewed epidemiological data from 1993-2004 and identified certain trends. TB case rates decreased in both groups from 1993-2004: 28/100,000 to 11.3/100,000 in USB AAs and 9.2/100,000 to 1.1/100,000. The percent of TB cases in persons with a history of substance abuse increased in both groups from 1993-2004: 26% to 34% in USB AAs and 16% to 27% in whites. Estimated HIV co-infection in persons reported with TB decreased in both groups from 1993-2004: 21.3% to 16.4% in USB AAs and 8.6% to 4% in whites.

The percent of persons with TB diagnosed in a correctional facility was 6% in USB AAs and 3% in whites from 1993-2004. The percent of TB cases in homeless persons was ~10% in both USB AAs and whites from 1993-2004. The percent of TB cases in unemployed persons in two years prior to diagnosis was relatively the same between USB AAs and whites. Reported TB cases by completion of therapy were relatively similar in both groups from 1993-2002: 85% in USB AAs and 86% in whites.

Overall, the 1993-2004 epidemiological data showed that AAs represented the largest group of TB cases among USB persons. TB case rates in USB AAs were consistently ~8 times higher than those of whites. TB cases in AAs with HIV co-infection, a history of substance abuse and incarceration were relatively higher than those in whites. Minimal progress was made in reducing the gap between USB AAs and whites over the ten-year period.

ACET previously called for presentations, increased research and resources to highlight the historic high case rate of TB among AAs in the Southeast. CDC and ACET convened a national meeting in May 2003 to raise awareness of the TB disparity and solicit support to decrease TB in AAs. CDC conducted several activities in response to recommendations made during the 2003 national meeting. CDC issued supplemental funding for Georgia, South Carolina and Chicago, Illinois to conduct demonstration projects and identify innovative strategies to improve TB screening, diagnosis and treatment in high-risk AA communities. All three grantees incorporated communication and public awareness campaigns into the demonstration projects.

CDC developed and disseminated fact sheets and *The TB Challenge: Partnering to Eliminate TB in AAs* newsletter. CDC funded a TBESC project in 2003 to address TB among AAs in the Southeast and identify and overcome barriers to treatment adherence to LTBI and TB disease. CDC convened the May 2006 summit in follow-up to the 2003 national meeting.

Several goals and objectives were established for the summit. Efforts to raise awareness of the problem would be established. Accomplishments from the 2003 national meeting would be expanded. Linkages and networks would be created to develop ongoing strategies to address the problem. Political will to address the TB disparity would be reinvigorated. Commitment to and participation in this effort would be broadened beyond TB programs. Strategies that could be implemented and sustained would be formulated and stimulated. Actions to contribute to TB elimination for AAs would be catalyzed.

The summit participants would be expected to understand the importance of TB as a health issue in the AA community; learn about research findings regarding TB in the AA community; and formulate and commit to implementing action items over the next year. A Summit Planning Committee was formed with representation by CDC, ACET and other organizations to guide the planning process and complete several tasks. More than 100 persons from CDC, HHS, TB prevention programs, professional associations and academic institutions attended the summit.

Sessions during the summit included keynote speeches from public health leaders; presentations on state-of-the-art research and demonstration projects; a panel of patients who described challenges with TB diagnosis and treatment; and breakout sessions for the participants to develop concrete action items that could be realistically implemented in the

upcoming year. Overall, the summit renewed dialogue and interest among diverse institutions and partners to address TB in the AA community.

Partner Perspective. Dr. Rachel Royce, of RTI International, co-chaired the Summit Planning Committee and provided a partner's perspective of this event. A disproportionate number of TB cases in the United States are reported among AAs compared to whites. The published literature and surveillance data do not address the descriptive and analytic epidemiology of TB in AAs because USB AAs are combined with FBPs. However, the epidemiology of TB would clearly be different for these two groups.

Based on annual reports, TB rates are ~8 times higher in AAs compared to whites. Epidemiologists should have the ability to extract anonymous surveillance data from Report of Verified Case of TB forms to address this disparity, but the release of and permission to use these data are granted on a state-by-state basis. Epidemiologists have made several recommendations to overcome these barriers. A research agenda should be developed. Basic studies should be conducted because TB epidemiology is local. Surveillance data should be collected to report numbers and rates for USB AAs. Epidemiologists should be given access to surveillance data to perform independent analyses.

Several efforts are underway to respond to the epidemiological recommendations. TBESC formed a research committee to develop a research agenda and also established a workgroup to focus on TB in AAs. A suggestion was made at the recent NTCA conference to gather surveillance data on TB rates in USB AAs. Of 14,517 TB cases reported in 2004, AAs represented 45% of all USB cases. Of 2,975 cases among USB AAs, 35% were reported by eight Southeastern states.

TBESC designed a conceptual model to better understand the rationale for active TB and LTBI disparities in AAs. TBESC determined that the most important factors contributing to TB disparities in AAs were a higher community prevalence; longer periods of time to accurately detect and treat cases; and poorer rates of treatment initiation, adherence and completion. These findings emphasize the need to develop interventions at social, cultural and structural levels.

Small and homogenous groups of organizational peers participated in the summit breakout sessions to develop action plans that could be realistically implemented over the next year. However, the participants were not charged with reaching consensus. Dr. Royce highlighted key action items proposed during the summit, but she pointed out that these activities only represent a sample of the full action plans.

State Offices of Minority Health (OMHs) proposed three major action items. OMHs should partner with DTBE to broadcast a nationwide satellite conference on TB awareness. OMHs should engage at least five grassroots organizations in developing regional strategic plans on TB elimination in the AA community. OMHs should distribute TB educational materials to community-based organizations (CBOs) and other partners within states.

Professional organizations proposed five major action items. A consortium and virtual network should be developed to identify call lists, create an outbound call center, and design and launch a marketing campaign. A workshop on TB in AAs should be held at the annual meeting of the National Association of Black Social Workers. A position paper on TB in AAs should be presented at the annual meeting of the National Black Nurses Association.

A presentation should be made on TB in AAs at the meeting of the Atlanta Area of Concerned Black Clergy and other churches. TB testing should be incorporated into health fairs and mobile testing units. The National Medical Association (NMA) recently requested 2,000 brochures on TB in AAs to distribute during its national meeting. Efforts are underway for CDC to make a presentation during NMA's national meeting.

TB prevention programs and other TB grantees at state and local levels proposed four major action items. RTMCCs should develop materials for healthcare providers to treat AAs with TB and post this information on web sites. A specific web page should be designed to target healthcare providers who serve AAs. TB prevention programs should collaborate with TB controllers to establish leadership from grassroots organizations. Each Historically Black Medical School should prepare and post an awareness e-mail to the listserve of its institution. Academic centers should contact the head of the steering committee to add TB to the National Center for Primary Health Care's health disparities list for AAs.

CDC proposed five major action items. CDC should use its National Center for Health Marketing to increase awareness of TB in AAs. CDC should ensure that the ACET web site contains up-to-date information. CDC should develop and disseminate culturally competent materials and linguistically appropriate services. CDC should hire a celebrity spokesperson to increase awareness of TB in AAs. CDC should update its surveillance system to collect data on TB in AAs.

Local and national advocacy organizations proposed two major action items. The organizations should form a consortium or coalition to develop a plan to leverage federal, private and public support for TB and other health disparities. Each organization should immediately make a commitment to integrate information provided at the summit into its individual programming efforts.

Several activities are planned to follow-up and monitor the action plans proposed during the summit. CDC and RTI International will facilitate ongoing communications by developing a listserve and web site for the summit participants, invitees and the public. Conference calls will be convened for the summit participants to report on implementation of the action plans and describe lessons learned. The conference calls will be structured as focus groups to assess the immediate and mid-term impacts of the summit on raising awareness and conducting other activities. Short- and mid-term outcomes of the summit and implementation of the action plans will be evaluated.

The cost of ~$69,000 to conduct the summit will be assessed. TBESC, RTI International, CDC and Cellestis made contributions ranging from $1,000-$52,000. However, RTI International, CDC, TB control programs, ACET members, national organizations and guest speakers also contributed time and in-kind support for the meeting facility, refreshments, materials, a summit web site and other services.

Strategies will be developed to overcome the following limitations. Important partners representing foundations, faith-based organizations (FBOs), academic centers, minority health centers, the media and politicians were not well represented at the summit. These partners must be engaged in future efforts. Funding must be leveraged and sustained over time to intensify data collection and other activities because dollars for summit-related efforts are not earmarked in the CDC budget.

External partners are receptive and willing to provide assistance, but no mechanisms have been designed to develop these groups as formal partners and provide linkages to the broader TB field. The lack of data on TB in AAs contributes to an incomplete understanding of the underpinnings of the disparity. The problem is under-recognized, under-funded and undervalued. The need for significant epidemiologic research must be addressed before science-based interventions can be formulated.

The summit resulted in both immediate and long-term impacts. Dialogue and interest in TB disparities in the AA community were rekindled across institutions. The participants made commitments to try to achieve specific goals and action items over the next year. New partners that understand the culture and dynamics of the AA community and have access to this population were engaged. Opportunities were provided for state and local TB controllers to link to resources in the AA community. Summit participants will maintain communications over the next year. Progress toward implementing the action plans will be measured. Activities will be monitored and evaluated to determine the extent to which social mobilization occurred.

Overall, the summit might serve as a social mobilization model that can be tailored to and replicated at the regional, state or local level. The need to convene additional summits in the future will be determined. Evaluation indicators extracted from cooperative agreement activities on TB in AAs will be analyzed. Opportunities are available to recommend the implementation of a TBESC-wide study on the epidemiology of TB in AAs. New data and knowledge could potentially benefit other ethnic groups.

The ACET members made several suggestions for CDC to consider in its future efforts to expand the summit activities and reduce TB disparities in the AA community.

- Studies should be designed to focus on the biological factors of AAs.
- Effective strategies should be applied to engage academic medical centers and minority health centers as full partners in TB disparity activities. These groups are absolutely essential in making an impact on the prevention and treatment of TB in the AA community. For example, web-based courses with

continuing medical education credits could be offered to providers who serve AAs at high risk for TB. The Health Resources and Services Administration (HRSA) could establish measurable indicators for community health centers (CHCs) to provide TB screening and follow-up to clients. HRSA could collaborate with ACET in monitoring these indicators over time.

- Outreach should be targeted to all undergraduates at Historically Black Colleges and Universities (HBCUs). Many of these students will pursue careers in the law, politics and other non-health fields that could have a strong influence on reducing disparities.
- Qualitative data should be collected from AAs at high risk for TB, such as their health priorities and motivating factors.
- Denominator data on TB attack rates between AAs and whites should be gathered and compared in the categories of unemployment, homelessness and substance abuse.
- Strong efforts should be made to overcome legislative barriers and engage groups that played an important role in HIV/AIDS among AAs, such as the National Conference of State Legislators and the Congressional Black Caucus.
- Future research projects should be designed to identify common underlying factors that contribute to disparities among AAs for TB, heart disease, cancer, diabetes and other conditions. Interventions should be developed to specifically target these common underlying factors in individuals rather than focusing on the disease. For example, the CCID centers could jointly develop a strategic plan and allocate funds to address the same populations in the AA community at high risk for TB, HIV, STDs, and other chronic or communicable diseases.
- Participants of CDC's partner leadership conference should be made aware of and given access to the web site and listserve for the TB disparities summit.
- An NMA representative should be invited to serve on ACET as a liaison member to facilitate ACET's access to and regular communications with HBCUs, FBOs and other influential groups in the AA community. Alternatively, an NMA representative should be invited to attend ACET meetings when TB disparity issues are placed on the agenda.
- CDC should prioritize TB as a health disparity at the highest level of the agency to encourage HHS to take a similar action. The CDC OMH should develop concrete strategies to facilitate this activity. Providers will continue to ignore TB as a health disparity in the AA community until the disease is listed as a health disparity at the highest federal level. Dr. Fenton should serve as an internal champion in this effort by conveying ACET's request to CCID.
- ACET and CDC should engage in an extensive discussion during a future meeting on innovative strategies to reduce TB disparities in the AA community. Traditional approaches have not made a significant impact because AAs only account for 12% of the total U.S. population, but represent 45% of the TB burden in the United States. Several approaches should be

considered to address this issue. DTBE could target funding directly to CBOs. DTBE could encourage grantees to utilize funds in a more cost-efficient manner and target cost-savings to the reduction of TB disparities in the AA community. DTBE could serve as the national program to take leadership for and coordinate efforts with local programs.

- Effective interventions and best practices should be compiled from geographical areas with demonstrated success in decreasing TB rates in AAs. These resources should then be distributed to jurisdictions with stable or increased rates. DTBE should take the lead in coordinating this effort.
- DTBE should strongly encourage grantees to partner with local TB control programs in better understanding the local TB epidemiology and promoting TB screening.
- DTBE should closely collaborate with state and local health departments to enhance grantee capacity in accessing and outreaching to hidden and poor populations and persons at high risk for TB.

The federal agencies made several remarks in follow-up to ACET's suggestions and comments. Dr. Hazel Dean, of NCHSTP, was pleased to announce that the City of Atlanta mayor made a commitment to use a portion of local resources to support CDC's future efforts in reducing TB disparities in the AA community.

Dr. Theresa Watkins-Bryant, the HRSA *ex-officio* representative, emphasized HRSA's strong commitment to ensuring that CHCs prioritize clinical quality. HRSA is in the process of developing a new "Clinical Quality Initiative" to facilitate this effort. Dr. Watkins-Bryant also announced that several developments occurred at the local level following the summit. A representative from Howard University was unable to attend the summit, but has expressed a strong interest in becoming involved in future activities to reduce TB disparities in AAs. An FBO in New York City offered to organize a group of ministers to listen to a presentation from CDC. The ministers would then convey key points from the CDC presentation to their respective congregations.

Dr. Castro reminded ACET that DTBE developed a formula to reallocate and prioritize TB resources. The formula was based on local epidemiologic profiles of priority TB patient populations, such as patients with HIV/TB co-infection, incarcerated persons, FBPs and racial/ethnic minority groups. However, Dr. Castro pointed out that the realignment of resources is a complex issue because funds could actually be diverted. For example, grantees could be forced to decrease or eliminate outreach workers and other services. Dr. Castro welcomed guidance from ACET on effective strategies that could be applied to make existing TB programs culturally competent.

Dr. Fenton agreed with ACET on the need to use resources more efficiently and effectively. At the division level, Dr. Fenton asked Dr. Castro to identify opportunities in the DTBE budget to realign resources and directly fund CBOs. At the center level, Dr. Fenton announced his plans to recruit a new Associate Director for Program Integration by the end

of 2006. The duties of this position will include identifying NCHSTP's investments in states and determining opportunities for synergies.

This strategy will allow NCHSTP to encourage state grantees to take a more holistic approach to the prevention of HIV, STD, TB and viral hepatitis. For example, residents of poor, urban and socioeconomically deprived communities who present to CDC-funded programs could be offered HIV testing, TB screening, hepatitis B vaccination, and other infectious disease prevention interventions.

Dr. Fenton explained that the summit received little media attention because the NCHSTP media team is undergoing significant capacity issues. CDC expressed concerns about the potential for the media team to be overburdened and unable to respond to inquiries resulting from the summit. As a result, NCHSTP did not launch an aggressive media campaign for the summit. However, Dr. Fenton pointed out that NCHSTP's reduction of proactive media activities is temporary. NCHSTP intends to fully support the production and dissemination of the final summit report and other activities.

Dr. Fenton informed DTBE of three areas where the syphilis elimination model could be replicated to decrease TB disparities in AAs. First, local jurisdictions where syphilis rates continued to decline in AAs were identified. Site-specific research projects were developed to determine successful interventions and identify best practices in these geographical areas.

Second, ten jurisdictions across the country were found to be responsible for 50% of all reported syphilis cases. Instead of developing national approaches, prevention interventions for syphilis were designed to maximize the impact of activities specifically in these ten geographical areas. Third, funding was directly allocated to CBOs to develop more culturally competent initiatives to advance syphilis elimination efforts. The funding also resulted in mobilizing communities around syphilis and enhancing partnerships among CBOs, communities and health departments.

Dr. Fleenor advised CDC to take caution in applying syphilis, HIV and other disease models to reduce disparities in TB because. These interventions are based on behavioral changes, while TB is spread regardless of behaviors. Instead, CDC should place stronger emphasis on the guiding principles of TB control to reduce TB disparities in the AA community. For example, the local TB epidemiology in Birmingham, Alabama and geographic information systems (GIS) data indicate that the highest prevalence in TB consistently occurs in poor neighborhoods with limited access to the healthcare system and little value placed on preventive therapy. Dr. Fleenor suggested that CDC design effective strategies and allocate additional funding to conduct more TB screening, increase LTBI detection, and deliver interventions directly to these communities.

Update on TB in Hmong Refugees

Dr. Drew Posey, of DGMQ, covered the following areas in his report. Of 15,819 Laotian Hmong refugees in Wat Tham Krabok, Thailand, 15,256 resettled in the United States from 2004-2006 and 563 remain in Thailand. The 1991 TIs defined a "standard" TB screening algorithm for immigrants and refugees as a chest x-ray for persons ≥15 years of age and three acid-fast bacillus (AFB) sputum smears for persons with chest x-rays suggestive of active TB. No cultures were required.

Smear-positive persons were required to postpone travel until treatment was initiated and smear-negative results were obtained. Those individuals were allowed to complete TB therapy in the United States if a Class A waiver was obtained. A TB examination could be performed up to 12 months prior to travel for persons with no TB classification and up to six months prior to travel for persons with a TB condition. However, individuals could develop TB during this time lag. Smear-negative persons were classified as B1 and persons with findings of inactive disease on chest x-ray were classified as B2.

To address concerns about TB in refugees, the standard TB algorithm was expanded in May 2004 to include (1) *M.tb* cultures and drug susceptibility testing (DST) for refugees with TB signs or symptoms; (2) refugees with TB or chest x-ray findings highly suspicious of TB; and (3) refugees with negative sputum smears. The expanded TB algorithm was modified in February and June 2005 due to the detection of four MDR-TB cases in the Thailand refugee camp and reports of active TB in both adults and children <15 years of age who had resettled in the United States. The final TB algorithm requires chest x-rays and tuberculin skin testing (TST) for all refugees ≥6 months of age and travel within three months of screening. The B2 classification was removed from the standard TB algorithm for Hmong refugees.

Of 369 TB cases diagnosed in Hmong refugees in Thailand as of June 30, 2006, 91 were culture-positive and 33 were MDR-TB. Of the 91 culture-positive cases, 52 were smear-negative and 7 were among children <15 years of age. Of the 33 MDR-TB cases, 48% were smear-negative. Of the 369 cases in Thailand, 323 completed treatment, 19 are currently receiving treatment, 4 refused treatment, 18 left the camp, and 5 are deceased.

CDC will continue to conduct a number of activities in further management of the resettlement. The directly observed treatment (DOT) program will be continued until the resettlement is completed. A DGMQ medical officer will soon be deployed to Bangkok. The International Organization for Migration (IOM) Laboratory will begin performing DST in Wat Tham Krabok beginning in August 2006 to reduce laboratory reporting times. This exciting new development will allow DST results to be known within four weeks of a culture becoming positive. CDC and DOS will continue to support the IOM Laboratory. An investigation is underway on TB cases in Wat Tham Krabok with positive cultures that were clinically surprising and submitted to CDC for genotyping.

During the February 2006 meeting, ACET unanimously approved a motion for DTBE to conduct a review of ongoing case management activities for Hmong refugees in Thailand. DTBE and DGMQ are continuing to discuss this effort and will attempt to deploy a team to Thailand prior to the end of the fiscal year on September 30, 2006. ACET members and DTBE have already developed indicators for the case management review.

CDC will convene a conference call in August 2006 with states that have been most impacted by the Hmong resettlement. CDC will use the conference call as an opportunity to provide updated information to the states and address issues or concerns. The California Department of Health Services sent a letter to the HHS Secretary requesting information on HHS's commitment and response to the Hmong situation and future plans. HHS forwarded the letter to CDC for a response. CDC's official response is currently being cleared by DTBE.

Domestic Follow-up of Hmong Refugees Resettled in the United States

Ms. Kai Young, of DTBE, presented preliminary findings from the Hmong resettlement program. Of 15,256 Hmong refugees who resettled in the United States from 2004-2006, 5,752 resettled in California, 5,123 in Minnesota, and 3,234 in Wisconsin. Of 726 refugees who arrived to the United States with a B-notification status, 305 resettled in California, 234 in Minnesota, 143 in Wisconsin, and 44 in other states. Based on the U.S. total, 42% of Hmong refugees with a B-notification status resettled in California, 32% in Minnesota, 20% in Wisconsin, and 6% in other states.

Of 726 refugees who arrived to the United States with a B-notification status, ~300 were treated overseas. To date, 542 have completed domestic evaluation. Of 14 cases diagnosed with a B-notification status, four were treated overseas. Three of these four cases were MDR-TB. Of 53 TB cases diagnosed in Hmong refugees in the United States since 2004, California reported 30, Minnesota reported 13, Wisconsin reported 8, and two other states reported 2. California reported six of its cases as MDR-TB and Minnesota reported one MDR-TB case. Of the 53 cases, 39 were classified as having no apparent disease at the time of overseas screening.

CDC identified several improvements after the resettlement was temporarily halted in January 2005 to enhance the screening process. The number of TB cases in Hmong refugees dropped from 48 to 5. The TB case rate dramatically decreased from 508/100,000 to 86/100,000. The number of refugees with a B-notification status decreased from 10 to 4. The number of MDR-TB cases decreased from 6 to 1. The number of cases in children <15 years of age decreased from 18 to 1.

Dr. Martin Cetron, the DGMQ Director, reported that CDC is taking proactive measures to apply lessons learned from the Hmong resettlement to the much larger resettlement of ~150,000 Burmese refugees. The Burmese resettlement was recently launched and will

occur over the next 10-15 years. CDC is determining whether the case management indicators ACET and DTBE developed for Hmong refugees can be incorporated into existing databases for Burmese refugees. In addition to deploying a DGMQ medical officer to Bangkok, CDC will also allocate funds to build capacity and establish monitoring systems for the Burmese resettlement.

Several ACET members made suggestions for CDC to consider in the Hmong and Burmese resettlements. Interventions should be delivered to Hmong refugees with MDR-TB who are still being treated overseas. Earlier interventions could lesson the burden on states when refugees resettle in the United States. Data on Hmong refugees with MDR-TB who remain in Thailand should be analyzed and used to inform the Burmese resettlement. The feasibility of treating MDR-TB cases in the setting of an overseas screening program should be evaluated.

Update on TIs for Overseas TB Screening and Treatment

Dr. Posey described changes to, the implementation plan for, and oversight of TIs for panel physicians. The 2006 TIs require comprehensive diagnostic testing with sputum smears, cultures and TST in children 6 months to 5 years of age. Medical evaluations are required for children $\geq$6 months of age. The validity period of medical examinations was shortened to three months. TB treatment must be completed in its entirety overseas with a DOT program in accordance with the American Thoracic Society (ATS)/CDC/Infectious Diseases Society of America (IDSA) guidelines. DST results must be used to guide therapy.

The following algorithm is included in the 2006 TIs. Children 6 months to 5 years of age will receive a chest x-ray and TST. Persons $\geq$6 years of age will receive a chest x-ray. Three sputum smears and cultures will be required for persons with signs or symptoms of TB or a chest x-ray that suggests TB or confirms HIV. DST will be performed on persons with positive cultures. CDC distributed the 2006 TIs to ACET and NTCA for review and comment; revised the document based on this input; cleared the revised document; and is collaborating with DOS on finalizing the document. CDC will disseminate the final TIs and detailed implementation plan to ACET, NTCA and other organizations after the review and clearance process is completed.

The DGMQ Quality Assistance Program (QAP) will lead the implementation of the new TIs. QAP will collaborate with DTBE, DOS, IOM, ministries of health (MOHs), private organizations, hospitals and other entities that can play a key role in developing, providing and implementing TB services and the infrastructure for the new TIs.

A phased rollout is planned to initially introduce the new TIs to "high-priority" countries defined by immigration patterns, refugee re-settlements, number of U.S. foreign-born cases, and number of TB notifications. The TIs would then be implemented in all areas of the

world because DOS immigration laws require all countries to use the same process to screen immigrants.

QAP will implement the new TIs by making in-country site visits, training consular officials and panel physicians, identifying culture facilities, and identifying treatment programs. Consular officials and states will then be notified in writing of the time to begin using the new TIs. An evaluation process will be launched after the new TIs are implemented. During this time, panel physicians would be eligible for certification and medical records would be reviewed. To support the TI implementation plan, QAP is developing a new database with the following features: (1) linkages to GIS software and CDC's EDN system; (2) information on panel sites and previous evaluations; and (3) improved oversight. QAP's budget and personnel for the new TIs will be outlined in the written implementation plan.

Overall, CDC is using its legal mandate to provide screening overseas in a manner that will benefit TB control programs and communities. A study that was published in 2005 emphasized the value to the U.S. government of investing in TB programs overseas. The Vietnamese consulate recently informed CDC that local consulates, MOHs and governments would most likely appreciate and strongly support the new TIs because the process will result in stronger expertise and infrastructure for overseas TB programs.

Several ACET members made suggestions for CDC to consider in implementing the new TIs for panel physicians.

- CDC should partner with Australia and Canada because these countries also have large immigrant populations. Three countries rather than the United States alone would be in a better position and have more resources to manage TB and MDR-TB cases in immigrants who resettle.
- CDC should conduct a project to assess linkages that were made with the overseas public health system for Hmong refugees with MDR-TB who refused therapy or left the camp. Findings from this evaluation should be used to inform the Burmese resettlement and expand TB capacity overseas.

In response to ACET's suggestions, Dr. Cetron confirmed that the United States regularly communicates with the governments of four other major receiving countries of immigrants: Australia, Canada, New Zealand and the United Kingdom. These collaborative efforts provide the countries with opportunities to learn lessons, share data and leverage resources. CDC will host the next multi-country meeting in September 2006 in Atlanta, Georgia.

Dr. Cetron also informed ACET that the new TIs contain flexible language on potential waivers for MDR-TB cases. Resources would be allocated to states that express an interest in receiving and managing MDR-TB cases from other countries. Dr. Cetron announced that discussions are underway for DHS to give responsibility to HHS for the oversight and management of panel physicians. However, HHS emphasized its inability to undertake this effort as an unfunded mandate and notified DHS of resources that would be

required for the registration process, certification, monitoring, training, user fees and other issues.

Overview of Global Disease Detection (GDD) Funding

Dr. Thomas Navin, of DTBE, described the joint DGMQ/DTBE project to build capacity in Thailand. A Congressional appropriations committee commended CDC for its role in strengthening the capacity of the public health community at both domestic and international levels to respond to global threats. Congress also noted the purpose of the GDD system. Worldwide technical support would be provided to ensure rapid and accurate diagnosis of emerging infectious disease events. A secure link would be provided among CDC, clinicians, laboratories and the World Health Organization to ensure real-time reporting of emerging threats. Funding appropriated to GDD increased from $11.6 million in FY'04 to $33.5 million in FY'06.

DGMQ and DTBE established three goals for the joint project in Thailand. Ongoing collaborative efforts will be expanded with the Thai MOH to improve TB control in Thailand. TB screening of prospective U.S.-bound Burmese refugees will be enhanced. TB will be controlled. Funding of $717,500 per year for three years will be allocated to the joint project with DGMQ, DTBE, IOM, and the Thailand MOH. DGMQ and DTBE identified five objectives to achieve the three goals of the project. Activities DTBE will conduct to achieve three of the five objectives are summarized below.

First, capacity of the IOM, central and provincial laboratories to utilize rapid culture methods, provide DST of first- and second-line drugs, and implement a quality assurance process will be strengthened. The following activities will be conducted for the laboratory quality assurance process: (1) review the initial capacity and performance of laboratories, (2) develop standard operating procedures, (3) create indicators to measure laboratory performance, (4) collect baseline data on performance measurements, (5) provide training to laboratory staff in Thailand, (6) conduct periodic reassessments, and (7) apply lessons learned from this project to future activities.

Second, the Active TB Surveillance Project (ATSP) will be expanded beyond the four current provinces in Thailand. ATSP provides TB program monitoring of public and private facilities, routine HIV testing, linkages to HIV care, electronic data recording and reporting, and operational and clinical research, particularly in TB/HIV co-infected patients. Preliminary data from ATSP indicate the following results. Routine surveillance underestimates TB reporting in various provinces by ~17%. Reporting and standards of care in private sector clinics is less than those in public sector clinics. In various provinces, 15%-40% of TB patients are co-infected with HIV. Of all HIV-positive patients co-infected with TB, >90% have CD4 counts <200 ml.

Third, lessons learned from the Hmong experience will be applied to the Burmese settlement, other countries in the region and beyond. Strategies used in the project and the cost and impact of these activities will be documented. The results will serve as a basis to conduct evaluations, determine the impact of the overall project, and convince other countries to also undertake this effort. Training and education will be provided and educational materials will be distributed in Vietnam, Cambodia and the Philippines. Activities will eventually be expanded to China, India, Malaysia and Indonesia based on the success of the project.

Dr. Luis Ortega, of DGMQ, described activities DGMQ will conduct to achieve the remaining two objectives of the joint DGMQ/DTBE project in Thailand. First, data management will be strengthened. Capacity to detect TB and rapidly identify MDR-TB in U.S.-bound refugees will be improved. TB outbreaks in refugee camps will be reported in a timely manner. The process to electronically transfer health information to CDC will be refined. Existing measures for data security, confidentiality and protection will be retained.

CDC and the Thai MOH will redesign existing network systems and other databases to exchange information. The enhanced data management system will (1) facilitate expert clinical consultation for MDR-TB cases; (2) reduce the time in submitting information on U.S.-bound refugees to state and local health departments; and (3) strengthen capacity to provide health assessments and follow-up of refugees who resettle in the United States in a timelier manner. DGMQ and IOM are creating a platform to enhance the data management system.

The refined data management system will standardize, expedite and facilitate access to medical data by CDC and health personnel at state and local levels. This activity will particularly focus on TB and other conditions defined as a "public health priority" in refugee health and resettlement programs. CDC expects that the improved data management system will reduce the amount of time and decrease the level of human resources required to enter data at U.S. quarantine stations in processing new arrivals.

Second, healthcare workers (HCWs) will be trained overseas to enhance regional control of MDR-TB cases in U.S.-bound refugees. A comprehensive training program will be developed and targeted to HCWs overseas to facilitate this effort. The training program will be initially targeted to Thailand, Cambodia and the Philippines and eventually expanded to India, China, Malaysia and Indonesia based on successful evaluation results. The overseas training program is expected to reduce the number of TB and MDR-TB cases in the United States that is attributable to refugees who resettle from Southeast Asia. The curriculum for the training program will be coordinated with the implementation of the new TIs.

DGMQ will closely partner with IOM in enhancing the data management system and developing the HCW training program. However, other international governments, agencies and NGOs that provide refugee health services will be engaged as well. DTBE will visit and assess the quality of the IOM microbiology laboratory in Thailand and provide a written report of the findings and recommendations from the evaluation.

ACET commended CDC on its success in receiving GDD funds for the joint DGMQ/DTBE project to build capacity in Thailand. The members made two suggestions for CDC to consider in further development of this initiative. First, the tremendous resources and expertise RTMCCs have developed should be utilized to create the overseas HCW training program and curriculum. Second, measures and indicators developed by TBESC projects should be used to analyze the TB incidence and clinical status of the refugee population in Thailand.

With no further discussion or business brought before ACET, Dr. Kawamura recessed the meeting at 4:35 p.m. on July 26, 2006.

Current ACET Business

Dr. Kawamura reconvened the meeting at 8:36 a.m. on July 27, 2006 and entertained a motion to accept the previous meeting minutes. The motion was properly moved and seconded by Drs. Gonzales and Fluck, respectively. The February 15-16, 2006 ACET Meeting Minutes were **unanimously approved** with no changes or further discussion.

The action items and agenda items raised over the course of the meeting are outlined below.

Action Items

- Dr. Fleenor will solicit a volunteer from ACET to serve on the new TBESC Research Committee.
- The new or acting Executive Secretary will distribute the following documents to ACET in preparation of the discussion at the next meeting on TB disparities in the AA community: (1) presentations made to ACET after the 2003 consultation on health disparities in AAs and (2) the report from the May 2006 summit on TB disparities in the AA community.
- The new or acting Executive Secretary will invite an NMA representative to the next ACET meeting to describe the role of this organization in addressing TB disparities in the AA community. The invitation will be extended in parallel to CDC's efforts to expand ACET's charter to include an NMA representative as a formal liaison member. CDC will inform the HHS Secretary that an NMA liaison member would play an important role in enhancing ACET's impact on TB disparities in the AA community.
- The new or acting Executive Secretary will invite representatives of NGOs to future ACET meetings to describe their roles in TB elimination efforts.
- DTBE will review the report of the May 2006 summit on TB disparities in the AA community to identify and make a presentation to ACET on successful models of collaboration between CBOs and federal agencies.

Agenda Items

- Update by NCHSTP on the public health agency accreditation process.
- Presentation by TBESC on ACET's potential role in the new advisory review process for research concepts, prioritization and recommendations.
- Presentation by TBTC on its science agenda and recommendations by ACET on TBTC's new priorities for the next five years.
- Updates by DGMQ on the following issues: (1) activities to designate physicians as CSs; (2) the remaining MDR-TB cases in Hmong refugees in Thailand; and (3) the Burmese resettlement, including data on TB rates and types of drug resistance in this population.
- Update on TB control efforts in FBPs: (1) report by DIHS on the impact of new border security activities on ICE detainees and (2) report by DTBE on TB drug resistance surveillance and other ongoing efforts in Mexico.
- Update on nucleic acid amplification testing and rapid diagnostics.
- Extensive discussion on TB disparities in the AA community.
- Presentation by NTCA on the decreased federal TB budget and requirements for TB control programs to conduct more activities with no additional resources. Presentation by the new NCHSTP Associate Director for Program Integration on efforts that will be made to address the smaller TB budget and demands for additional efforts at the local level.
- Presentation on the impact of TB incidence in the United States and Canada from Haitian refugees, particularly in Boston, Miami, New York City and Montreal.
- Update on new TB research opportunities by diverse groups: (1) resource perspective by Dr. Peter Small of the Gates Foundation and the ACET *ex-officio* member for NIH; (2) community perspective by the Treatment Action Group; and (3) advocacy organization perspective by the National Coalition for the Elimination of Tuberculosis. **[February 2007 meeting]**
- Presentation on successful models of collaboration between CBOs and federal agencies.
- Update by Dr. Fleenor (or his designee) on the CCID BSC and the proposed national center subcommittees or BSCs.
- Update by DTBE on the following issues in TB informatics: (1) efforts to improve the two-way exchange of data between local jurisdictions and CDC; (2) actions taken to reduce duplicate data entries, paperwork and other burdens at the local level; (3) strategies implemented to integrate state TB surveillance systems into the CDC National Electronic Disease Surveillance System; and (4) CDC's new approach of obtaining primary TB data from hospitals and clinics while bypassing health departments.

Update on the National TB Program Performance Indicators

Dr. Navin reported on DTBE's progress in readdressing the national TB program performance indicators. National objectives from the Government Performance and Results Act, the Program Assessment Rating Tool, *Healthy People 2010* and cooperative agreements are not evidence-based, were not produced through collaborative efforts with partners, and did not establish specific performance targets based on a rational and transparent process. DTBE formed an evaluation workgroup to address these issues.

The workgroup was charged with updating the national objectives to be results-oriented, articulate common priorities, focus attention on future performance, and define major aims of TB programs. The workgroup formed a national objectives subgroup to review potential objectives, prioritize and select the most urgent issues, and decide on performance indicators. The subgroup was represented by CDC, NTCA and the American Public Health Laboratory Association (APHL).

From the wide range of objectives that were initially reviewed, the subgroup narrowed its focus on 28 objectives supported by reliable national data. CDC, NTCA and APHL then voted on four TB program indicators of the highest priority: (1) increase timely completion of treatment; (2) decline TB rates; (3) improve contact identification, evaluation and treatment; and (4) ensure timely laboratory reporting.

The subgroup used CDC's existing goals management methodology to establish national performance targets. Future performance was forecasted based on current performance and methods were reviewed to establish ambitious, but realistic targets for the future. A percentage improvement over the forecast and the actual performance of well-performing states served as the basis of establishing targets. However, the subgroup raised several concerns during the review process, such as inconsistent methods used by states to calculate variables; unrealistic forecasts and targets for children <5 years of age; difficulties in obtaining denominator data; the use of rates rather than numbers; and perceived consequences at the state level in failing to meet the performance targets.

DTBE will take several actions to resolve these concerns. Data from the U.S. Census Bureau will be used to develop and distribute denominator data to states and local jurisdictions. Each state will be given flexibility to establish its individual performance targets based on local TB epidemiology. The California TB Indicators Project will be used as a model in developing a program monitoring tool for states. States have been assured that the performance targets were designed to inform a self-evaluation process and are not intended to serve as a punitive measure. Dr. Navin requested ACET's input on strategies DTBE can apply to further refine the national TB program performance indicators.

ACET commended DTBE on its outstanding efforts in establishing national TB targets and made a commitment to support this important activity. Several members suggested actions DTBE could take to enhance this process.

- The target of a 0 TB case rate in children <5 years of age should be more realistic because this indicator is not consistent with the pathogenesis of TB.

Children can become infected during the time lag between the onset of symptoms and the detection and treatment of TB. The target of a 0 TB case rate should be limited to U.S.-born children and foreign-born children who have resided in the United States >5 years. Foreign-born children who have resided in the United States <5 years should not be included in this performance indicator.

- The model that was used to develop the TB treatment guidelines should be replicated. For example, ATS, CDC and IDSA jointly determined whether treatment approaches were based on solid evidence, empiric data, consensus opinion or anecdotal data.
- New performance indicators should be established in three areas: (1) the number of deaths before TB diagnosis; (2) the number of deaths while on TB treatment; and (3) acquired TB drug resistance and transmission.
- Confidence intervals should be incorporated into the national objectives to determine whether differences in performance among states can actually be measured.
- Self-reported data collected from states should be validated for accuracy because this information will be used to measure the performance indicators.
- Data should be gathered and used to compare differences between states with strong versus poor performance. Best practices and successful interventions should then be distributed to states with poor performance to ensure that all states have the same high level of standard.
- The performance indicator on decreasing the TB case rate in USB AAs should be stratified to analyze this population in rural versus urban areas.
- Exclusions should be incorporated into some of the performance indicators. For example, the target to increase the percentage of TB patients who complete treatment in $\leq$12 months to 93% will be extremely difficult to achieve at the national level due to side effects from and toxicity to first-line drugs. Patients who are placed on alternative regimens that require more than 12 months to complete should be excluded from this indicator.

Dr. Navin described additional activities CDC would conduct in response to ACET's solid input. State performance on TB cases in children <5 years of age would be reviewed and the target would be stratified by U.S.-born versus foreign-born children. The current performance indicators are priorities, but the national objectives would be expanded over time with additional targets. Each state submitted an evaluation plan to CDC describing its individual performance indicators. CDC would monitor these targets over time. An analytic project would be conducted to determine differences in TB case rates among USB AAs in rural versus urban areas.

Update on Global Fund Activities

Mr. Peter Mamacos, of the Office of the Global AIDS Coordinator (OGAC), reported on the U.S. government (USG) response to global HIV/AIDS and TB. The President's Emergency Plan for AIDS Relief (PEPFAR) is a five-year and $15 billion multifaceted approach to fighting HIV/AIDS in >120 countries. USG now leads the world in its level of support for the fight against HIV/AIDS. USG will provide nearly 70% of all international financing for the global struggle if the House and Senate approve the FY'07 budget request.

Of the $15 billion PEPFAR budget, $10 billion is allocated to the 15 focus countries; $4 billion to other PEPFAR countries; and $1 billion over five years to the Global Fund to Fight AIDS, Tuberculosis and Malaria (Global Fund). OGAC establishes policies to address HIV/AIDS and TB, but focus country teams are responsible for developing country operation plans (COPs) and implementing programs with partner agencies. Each COP must articulate the strategy the focus country will use to address HIV/AIDS and respond to HIV/TB co-infection. OGAC approves each COP.

The COPs must address the three PEPFAR goals established for the 15 focus countries: (1) support treatment for 2 million HIV-infected persons; (2) support prevention of 7 million new HIV infections; and (3) support care for 10 million persons infected and affected by HIV/AIDS, including orphans and vulnerable children. As of March 31, 2006, PEPFAR supported treatment for 561,000 persons in the 15 focus countries. In FY'05, >80% of PEPFAR's >1, 200 partners in the field were indigenous organizations.

TB is a high priority in PEPFAR because ~50% of all AIDS deaths in sub-Saharan Africa are due to TB. The FY'07 COP guidance directs country teams to support national TB and HIV/AIDS programs through the following activities. Routine TB screening should be promoted. HIV counseling and testing to all TB patients should be provided. All HIV-infected TB patients should be linked to HIV care and treatment, including anti-retroviral drugs and cotrimoxizole. All HIV-infected suspects should be linked to TB diagnosis and treatment using DOT short course (DOTS). Cross-referrals and access to prevention, care and treatment services should be ensured. Laboratory infrastructure should be developed to diagnose and manage TB and other opportunistic infections.

The Global Fund is a financing mechanism and an innovative model that allows each recipient country to develop its individual proposal. The Global Fund does not have a field presence, provide guidance or act as an implementing agency. Countries must establish a country coordinating mechanism (CCM) that represents all stakeholders. A recommendation was made for all CCMs to cover 40% of persons from civil society. USG has provided ~30% of all Global Fund contributions to date.

The Global Fund currently provides 67% of all international financing for TB and has made the following accomplishments to date. Training was provided to 1.5 million persons to deliver services for the treatment of AIDS, TB and malaria. As of June 2006, 119% of

DOTS treatment targets were achieved, 4,395 persons were treated for MDR-TB, and 1.4 million persons were treated under DOTS. A goal has been established to treat 3.5 million persons under DOTS by 2009. Current approvals include $900 million for TB programs and $144 million for combined HIV/TB programs. Programs have a five-year maximum ceiling of $1.45 billion for TB programs and $235 million for combined HIV/TB programs.

Local stakeholders develop and implement Global Fund programs in accordance with national plans. Global Fund policy stipulates that all grants with an MDR-TB component must procure second-line drugs through the Green Light Committee (GLC). To resolve resource issues, all Global Fund grants that address MDR-TB must now include a cost-sharing budget for GLC services. The Global Fund Secretariat defines an annual flat rate for each grant for GLC services that cannot exceed $50,000.

Grant performance is one of the Global Fund's most significant concerns at this time, including the ability of each country to meet its targets for HIV/AIDS, TB and malaria; determine and resolve problems with the grant; and identify, procure and distribute drugs in a timely manner. The Global Fund is also focusing on important issues related to management systems at the ministry level and human resources at the clinical level. The Global Fund has set aside $12 million to provide technical assistance to the countries and strengthen grant performance.

The Global Fund is also exploring the possibility of including specific questions on technical assistance during the parallel grant review for the upcoming cycle. For example, the technical review panel (TRP) would determine whether the applicant has existing capacity to implement the proposed project or specify the level of technical assistance the applicant would need to conduct activities. The TRP's findings and recommendations would then be incorporated as a condition of approving the grant.

Mr. Mamacos encouraged ACET to visit www.theglobalfund.org to obtain additional information on performance, disbursements and other aspects of Global Fund grants for each country. He also urged the members to submit applications to serve as experts on the TRP for Global Fund grants. ACET advised the Global Fund to gather information and document problems with grants by making country visits and asking staff in the field to provide input on performance at the local level.

New ACET Business

Dr. Kawamura opened the floor for the members to recommend activities ACET and CDC could conduct in the future in the ongoing effort to raise awareness of TB.

- Medical school curricula and training should be changed to strengthen awareness and knowledge of TB among students. A representative of the American Association of Medical Colleges should be invited to make a

presentation at a future ACET meeting on the actual steps involved in this process, such as including TB-related questions on medical board examinations.

- Collaborative efforts should be undertaken with the Centers for Medicare and Medicaid Services (CMS) due to the paradigm shift of this agency toward performance indicators and payment to providers who demonstrate improved health outcomes for patients. CMS established pay-for-performance indicators and Health Plan Employer Data and Information Set (HEDIS) measures for hypertension and diabetes, but TB might be another area of interest. A large proportion of TB patients also have or are at risk for diabetes and hypertension. A CMS representative should be invited to make a presentation at a future ACET meeting on the actual steps involved in including TB as a pay-for-performance indicator or HEDIS measure.
- The tremendous interest and focus on international health at both undergraduate and medical school levels should be used as an opportunity to highlight TB. Partnerships should be established with ATS and IDSA in this effort.
- Educational activities on TB should be targeted to infectious disease and pulmonary fellows and residents because these providers teach medical students.
- A presentation on the National Strategic Plan for TB Training and Education should be made at a future ACET meeting. ACET could use this opportunity to determine if objectives established for medical school training were achieved.
- Efforts should be made to incorporate TB into primary care, public health and occupational settings. For example, TB should be included in the public health curriculum when medical school students learn about disease control reporting. Educational messages should be delivered when each medical school student receives a TB skin test.
- Schools of nursing, pharmacy and social work and public health students at the master's level should be included in all efforts to incorporate TB into curricula.
- Geographical areas in the United States with high rates of delayed TB diagnosis and treatment should be identified. Solid information should be distributed to physicians, nurses, pharmacists and other providers in these jurisdictions to strengthen emphasis on the disproportionate burden of TB in racial/ethnic minority groups.
- Collaborative efforts should be undertaken with ATS to convene a TB session for infectious disease fellows during its conferences.
- TB education and messages should be targeted to family practitioners, pediatricians and other primary care professionals.
- A partnership should be established with the American Medical Association to administer a nationwide survey to physicians to determine current knowledge of TB.

- TB clinics should be encouraged to send fellows and residents on calls when DOT is administered to patients.
- Pharmaceutical companies should be encouraged to include TB in presentations on community-acquired pneumonia.
- Private providers should be encouraged to limit interventions to clinical recognition and diagnosis of TB only. Private providers should be informed of the important need for public health departments to administer TB treatment. Data show that TB patients have better outcomes when receiving care from public rather than private providers.

Closing Session

The participants applauded Dr. Kawamura's outstanding service as the ACET Chair; Dr. Fleenor's solid preparations in his new role as the incoming ACET Chair; and Dr. Valdiserri's tremendous contributions as the ACET Executive Secretary for the past eight years. Dr. Kawamura thanked CDC for the opportunity to serve on ACET as both the chair and a member. She was positive that ACET would continue to make important advances and contributions to TB elimination under Dr. Fleenor's leadership.

Dr. Valdiserri announced that Ms. Paulette Ford-Knights, the ACET Committee Management Specialist, has accepted another position in CDC and would no longer serve in this capacity as of the next meeting. The participants applauded Ms. Ford-Knights for providing excellent management and support to ACET for a number of years.

The next ACET meeting will be held on November 28-29, 2006. With no further discussion or business brought before ACET, Dr. Kawamura adjourned the meeting at 11:35 a.m. on July 27, 2006.

I hereby certify that to the best of my knowledge, the foregoing Minutes of the proceedings are accurate and complete.

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Date

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L. Masae Kawamura, M.D.
ACET Chair